A Quality Management Plan

Presented by

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A Quality Management Plan

Encompasses both quality assurance and quality control procedures and details the responsibility, scope, key indicators measured, sample size and frequency of these activities.

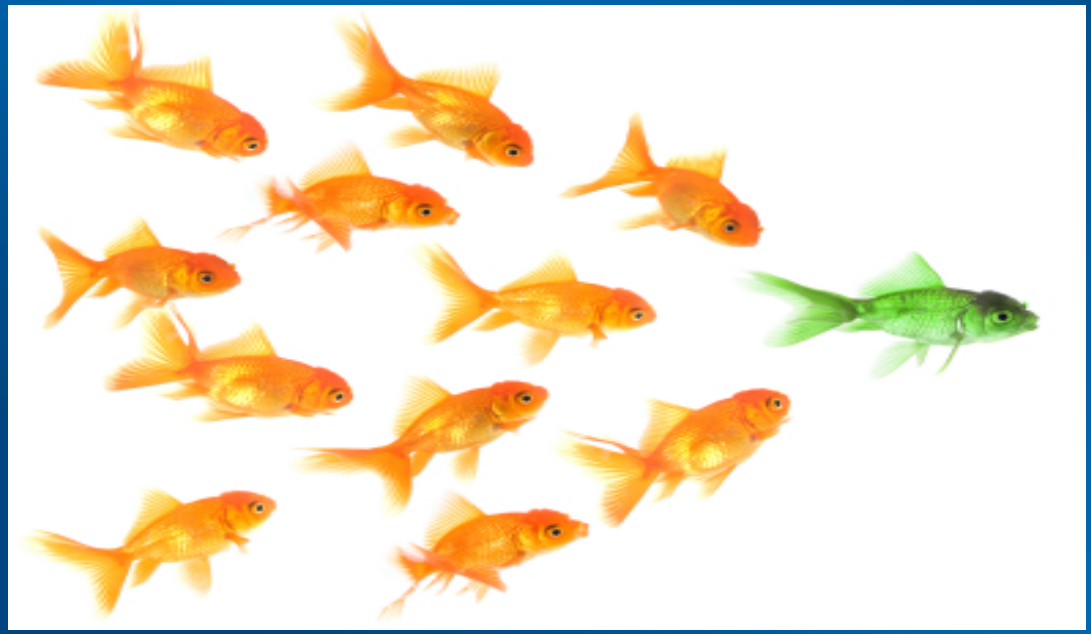
Why have a quality management plan?

- Monitors subject safety.
- Assists in maintaining compliance with the protocol.
- Develops proactive communication among study team members.
- Encourages early identification and resolution of study problems or concerns.

- Leads to overall reduction in external (FDA, sponsor) and internal (URMC) queries.

- Encourages conformity with Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), institutional policies and Federal regulations.

It also demonstrates that you as a leader are creating a quality environment at your site.



How to establish a quality management plan:

1. Incorporate all available quality assurance review tools:

- *chart audit tools:*
  source documentation/validation- the ALCOA method (attributable, legibility, contemporaneous, original, accuracy), Inclusion/exclusion criteria, study product/study device documentation, AE and SAE reporting documentation, informed consent process documentation, etc.
- *regulatory review tools*

How to establish a quality management plan:

2. Indicate the frequency and responsibility of the audits/reviews and what sample size will be used.

- *review of each signed consent form weekly beginning with PID#123.*
- *review of 100% of first three subject charts since RSRB approval of amendment 2 (date) for key quality indicators and then quarterly thereafter.*
- *100% review quarterly with sampling of* $\sqrt{N} + 1$

Summarize findings in a brief report and document corrective action and preventative action plans, any possible training issues, systemic problems and trends and assess for the root cause. Plan to re-evaluate any significant issues until resolved.

Quality Management Plan	
This quality management plan verifies that the clinical research is conducted according to the IRB approved protocol and in compliance with the ICH and GCP guidelines, Federal regulations and RSRB policies at the University of Rochester.	
Protocol title/#:	Principal Investigator:
RSRB #:	Date of IRB approval:
Projected accrual:	Study duration:
Risk level:	Participant duration:
Investigational product:	Date of site activation:
Frequency of QC audit: Initial review of first three enrollees @ 100% , monthly random sampling of √N + 1 informed consent process documentation	Frequency of QA audit: Quarterly after initial review, random sampling of square root of n + 1
Dates of QC audits:	Dates of QA audits:
1)	1)
2)	2)
3)	3)
Frequency of Regulatory review: prior to study start, biannually thereafter	Dates of regulatory reviews:
1)	1)
2)	2)
Quality Management Summary dates:	
1)	
2)	
Delegation of Quality Control and Quality Assurance:	
Study Coordinator/Regulatory affairs:	
Pharmacist/Unblinded Personnel:	
Biostatistician(randomization):	
Quality Control auditor:	
Quality assurance auditor:	
Data entry:	
Effective date of quality management plan:	
Annual review of quality management plan:	due by

A quality management plan is a process for continuous quality improvement so review it at least annually.

Haven’t done any QC/QA audits/reviews for any of your studies? Why not try one suggested today and document its use in a quality management plan.

Keep it simple!

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